CLAIMS

The invention is claimed as follows:

1. A method of modulating inflammatory and immune responses in a subject in need thereof, the subject having a first level of regeneration and tolerance factor (RTF) activity, and the method comprising altering the first level of RTF activity to a second level of RTF activity.

2. The method of claim 1, wherein the modulation of the immune response is immune activation and wherein the second level of RTF activity is lower than the first level of RTF activity.

3. The method of claim 2, wherein the method of enhancing the immune response is by inhibiting RTF activity.

4. The method of claim 3, wherein the method of inhibiting RTF activity is by administering to the subject an effective amount of a RTF antagonist.

5. The method of claim 4, wherein the RTF antagonist is selected from the group consisting of small molecules, peptides, and antibodies or a fragment thereof, wherein the RTF antagonist inhibits RTF by binding to RTF.

6. The method of claim 5, wherein the antibody is selected from the group consisting of monoclonal antibodies and polyclonal antibodies.

7. The method of claim 4, wherein the RTF antagonist inhibits cellular expression or synthesis of RTF.

8. The method of claim 7, wherein the RTF antagonist inhibits cellular RTF expression or synthesis by interfering with DNA encoding the RTF.

9. The method of claim 8, wherein the RTF antagonist is an antisense nucleic acid.

10. The method of claim 7, wherein the RTF antagonist inhibits cellular RTF expression or synthesis by inducing interference of RTF gene RNA.

11. The method of claim 10, wherein the RTF antagonist is an interference RNA.

12. The method of claim 11, wherein the interference RNA is a small interference RNA (siRNA).

13. The method of claim 11, wherein the double-stranded RNA is exogenous.

14. The method of claim 11, wherein the double-stranded RNA is expressed intracellularly.

15. The method of claim 2, wherein the activation of the immune response leads to apotosis of cancer cells.

16. The method of claim 15, wherein the cancer cell is ovarian carcinoma cell.

17. The method of claim 1, wherein the modulation of inflammatory responses is inhibiting inflammation wherein the second level of RTF activity is higher than the first level of RTF activity.

18. The method of claim 17, wherein the first level of RTF activity is increased to the second level of RTF activity is by inducing cellular expression of RTF.

19. The method of claim 17, wherein the first level of RTF activity is increased to the second higher level of RTF activity is by administering to the subject an effective amount of a RTF or a fragment thereof.

20. The method of claim 19, wherein the administered RTF or its fragment is isolated or purified from a mammalian cell.

21. The method of claim 20, wherein the mammalian cell is a T-lymphocyte.

22. The method of claim 21, wherein the T-lymphocyte is an activated T-lymphocyte.

23. The method of claim 20, wherein the mammalian tissue is a B-lymphocyte.

24. The method of claim 23, wherein the B-lymphocyte is an activated B-lymphocyte.

25. The method of claim 20, wherein the mammalian cell is a macrophage.

26. The method of claim 20, wherein the mammalian cell is a thymus cell.

27. The method of claim 20, wherein the mammalian cell is from fetalplacental tissue.

28. The method of claim 20, wherein the mammalian cell is a murine cell.

29. The method of claim 20, wherein the mammalian cell is a human cell.

30. The method of claim 19, wherein the administered RTF is an intracellular form having a molecular weight of about 70 kDa.

31. The method of claim 19, wherein the administered RTF is an external membrane form having a molecular weight of about 50 kDa.

32. The method of claim 19, wherein the administered RTF or its fragment is synthetic or produced by a recombinant process.

33. The method of claim 32, wherein the administered RTF or the fragment is synthesized from a nucleic acid sequence encoding an amino acid sequence of the RTF.

34. The method of claim 1, wherein the subject is a mammal.

35. The method of claim 1, wherein the subject is a human.

36. A method of treating cancer in a subject in need thereof, the subject having a first level of regeneration and tolerance factor (RTF) activity, and the method comprising altering the first level of RTF activity to a second level of RTF activity wherein the second level of RTF activity is lower than the first level of RTF activity.

37. The method of claim 36, wherein the method of lowering the first level of RTF activity to the second level of RTF activity is by inhibiting the level of RTF activity in the subject.

38. The method of claim 36, wherein the method of inhibiting the RTF activity is by administering to the subject an effective amount of a RTF antagonist.

39. The method of claim 38, wherein the RTF antagonist is selected from the group consisting of small molecules, peptides, and antibodies or fragments thereof, wherein the RTF antagonist binds to RTF.

40. The method of claim 39, wherein the antibody is selected from the group consisting of monoclonal antibodies and polyclonal antibodies.

41. The method of claim 38, wherein the RTF antagonist inhibits cellular expression or synthesis of RTF.

42. The method of claim 41, wherein the RTF antagonist inhibits cellular RTF expression or synthesis by interfering with DNA encoding the RTF.

43. The method of claim 42, wherein the RTF antagonist is an antisense nucleic acid.

44. The method of claim 41, wherein the RTF antagonist inhibits cellular RTF expression or synthesis by inducing interference of RTF gene RNA.

45. The method of claim 44, wherein the RTF antagonist is an interference RNA.

46. The method of claim 45, wherein the interference RNA is a small interference RNA (siRNA).

47. The method of claim 45, wherein the double-stranded RNA is exogenous.

48. The method of claim 45, wherein the double-stranded RNA is expressed intracellularly.

49. The method of claim 36, wherein the subject is a mammal.

50. The method of claim 36, wherein the subject is a human.

51. The method of claim 36, wherein the cancer is ovarian cancer.

52. A method of treating or ameliorating an inflammatory disorder or an autoimmune disorder or one or more symptoms thereof, the method comprising administering to a subject in need thereof a prophylactically or therapeutically effective amount of a regeneration and tolerance factor (RTF) or a fragment thereof.

53. The method of claim 52, wherein the RTF or the fragment is isolated or purified from a mammalian cell.

54. The method of claim 53, wherein the mammalian cell is a T-lymphocyte.

55. The method of claim 54, wherein the T-lymphocyte is an activated T-lymphocyte.

56. The method of claim 53, wherein the mammalian cell is a B-lymphocyte.

57. The method of claim 56, wherein the B-lymphocyte is an activated T-lymphocyte.

58. The method of claim 53, wherein the mammalian cell is a macrophage.

59. The method of claim 53, wherein the mammalian cell is a thymus cell.

60. The method of claim 53, wherein the mammalian cell is from fetalplacental tissue.

61. The method of claim 53, wherein the mammalian cell is a murine cell.

62. The method of claim 53, wherein the mammalian cell is a human cell.

63. The method of claim 52, wherein the RTF is an intracellular form having a molecular weight of about 70 kDa.

64. The method of claim 52, wherein the RTF is an external membrane form having a molecular weight of about 50 kDa.

65. The method of claim 52, wherein the RTF or the fragment is synthetic or prepared by a recombinant process.

66. The method of claim 65, wherein the RTF or the fragment is synthesized from a nucleic acid sequence encoding an amino acid sequence of the RTF.

67. The method of claim 52, wherein the RTF or the fragment is formulated with one or more acceptable pharmaceutical excipients.

68. The method of claim 67, wherein the RTF or the fragment is formulated as nanoparticles or microparticles.

69. The method of claim 68, wherein the nanoparticles or microparticles further comprising ligands for delivery of the nanoparticles or microparticles to a target tissue.

70. The method of claim 69, wherein the target is a T-lymphocyte.

71. The method of claim 69, wherein the target is a B-lymphocyte.

72. The method of claim 69, wherein the target is a macrophage.

73. The method of claim 67, wherein the RTF or the fragment is administered by a route selected from the group consisting of: parenteral, topical, nasal, pulmonary, ophthalmic, bucal, vaginal, transdermal, intrathecal, and oral.

74. The method of claim 52, wherein the subject is a mammal.

75. The method of claim 52, wherein the subject is human.

76. The method of claim 52, wherein the inflammatory disorder is arthritis.

77. The method of claim 52, further comprising the step of administering to the subject a TNF-α antagonists.

78. The method of claim 77, wherein the TNF-α antagonists is infliximab.

79. The method of claim 77, wherein the TNF-α antagonist is etanercept.

80. The method of claim 77, wherein the TNF-α antagonist is D2E7.

81. The method of claim 77, wherein the TNF-α antagonist is CDP571.

82. The method of claim 77, wherein the TNF-α antagonist is CDP870.

83. The method of claim 77, wherein the TNF-α antagonist is a thalidomide analog.

84. The method of claim 77, wherein the TNF-α antagonist is a phosphodiesterase type IV inhibitor.

85. A composition for enhancing immune response in a subject in need thereof, the composition comprising an effective amount of a RTF antagonist.

86. The composition of claim 85, wherein the RTF antagonist is selected from the group consisting of small molecules, peptides, antisense nucleic acids, interference RNAs, and antibodies or fragments thereof.

87. The composition of claim 86, wherein the antibody is polyclonal or monoclonal.

88. The composition of claim 86, wherein the antibody is monoclonal.

89. The composition of claim 86, wherein the interference RNA is small interference RNA (siRNA).

90. The composition of claim 85 further comprising a suitable pharmaceutical excipient..

91. The composition of claim 85, wherein the composition is suitable for administering to the subject by a route selected from the group consisting of: parenteral, topical, nasal, pulmonary, ophthalmic, bucal, vaginal, transdermal, intrathecal, and oral.

92. The composition of claim 85, wherein the composition is formulated as nanoparticles or microparticles.

93. The composition of claim 86, wherein enhancing immune response leads to apotosis of cancer cells.

94. The composition of claim 93, wherein the cancer cell is ovarian carcinoma cancer cell.

95. The composition of claim 85, wherein the subject is a mammal.

96. The composition of claim 85, wherein the subject is a human.

97. A composition for enhancing treating cancer in a subject in need thereof, the composition comprising an effective amount of a RTF antagonist.

98. A composition for treating or ameliorating an inflammatory disorder or an autoimmune disorder or one or more symptoms thereof in a subject, the composition comprising an effect amount of a regeneration and tolerance factor (RTF) or a fragment thereof.

99. The composition of claim 98, wherein the RTF or the fragment is isolated or purified from a mammalian cell.

100. The composition of claim 99, wherein the mammalian cell is a T-lymphocyte.

101. The composition of claim 100, wherein the T-lymphocyte is an activated T-lymphocyte.

102. The composition of claim 99, wherein the mammalian cell is a B-lymphocyte.

103. The composition of claim 102, wherein the B-lymphocyte is an activated T-lymphocyte.

104. The composition of claim 99, wherein the mammalian cell is a macrophage.

105. The composition of claim 99, wherein the mammalian cell is a thymus cell.

106. The composition of claim 99, wherein the mammalian cell is from fetalplacental tissue.

107. The composition of claim 99, wherein the mammalian cell is a murine cell.

108. The composition of claim 99, wherein the mammalian cell is a human cell.

109. The composition of claim 98, wherein the RTF is an intracellular form having a molecular weight of about 70 kDa.

110. The composition of claim 98, wherein the RTF is an external membrane form having a molecular weight of about 50 kDa.

111. The composition of claim 98, wherein the RTF or the fragment is synthetic or prepared by a recombinant process.

112. The composition of claim 111, wherein the RTF or the fragment is synthesized from a nucleic acid sequence encoding an amino acid sequence of the RTF.

113. The composition of claim 98, wherein the RTF or the fragment is formulated with one or more acceptable pharmaceutical excipients.

114. The composition of claim 98, wherein the RTF or the fragment is formulated as nanoparticles or microparticles.

115. The composition of claim 114, wherein the nanoparticles or microparticles further comprising ligands for delivery of the nanoparticles or microparticles to a target tissue.

116. The composition of claim 115, wherein the target is a T-lymphocyte.

117. The composition of claim 115, wherein the target is a B-lymphocyte.

118. The composition of claim 115, wherein the target is a macrophage.

119. The composition of claim 98, wherein the RTF or the fragment is administered by a route selected from the group consisting of: parenteral, topical, nasal, pulmonary, ophthalmic, bucal, vaginal, transdermal, intrathecal, and oral.

120. The composition of claim 98, wherein the subject is a mammal.

121. The composition of claim 98, wherein the subject is human.

122. The composition of claim 98, wherein the inflammatory disorder is arthritis.